

Services, Department of Education, and the United States Department of Agriculture. The Act does not apply to any portion of such facility that is used for inpatient hospital treatment of individuals dependent on, or addicted to, drugs or alcohol, or services provided in private residences. For additional information please view **Federal Register** Notice, 94 FRN 32136, or to see the statute in its entirety please view Public Law 107-110 (2001).

FOR FURTHER INFORMATION CONTACT: Pro-Children Act Liaison, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, N.E., Mailstop K-50, Atlanta, GA 30341-3717, (770) 488-5705, then press option 3.

Dated: October 4, 2002.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Proposed Measles, Mumps, Rubella (MMR) Vaccine Information Materials

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice with comment period.

SUMMARY: Under the National Childhood Vaccine Injury Act (42 U.S.C. 300aa-26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. Since the recommended interval between receiving rubella-containing vaccine and becoming pregnant has been revised from 3 months to 4 weeks, the vaccine information materials covering measles, mumps and rubella vaccine must be revised. CDC seeks written comment on proposed revised vaccine information materials for MMR vaccine.

DATES: Written comments are invited and must be received on or before December 9, 2002.

ADDRESSES: Written comments should be addressed to Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E-05, 1600

Clifton Road, NE., Atlanta, Georgia 30333.

FOR FURTHER INFORMATION CONTACT:

Walter A. Orenstein, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, NE., Atlanta, Georgia 30333, (404) 639-8200.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Public Law 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers, whether public or private, to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program.

Development and revision of the vaccine information materials have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines covered by this statutory requirement are diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, Haemophilus influenzae type b (Hib), varicella (chickenpox), and pneumococcal conjugate vaccine. Copies of the current vaccine information statements (VIS) for these vaccines, and instructions for their use, can be found on the CDC Web site at: <http://www.cdc.gov/nip/publications/vis/>.

Measles, Mumps & Rubella Vaccine

The Advisory Committee on Immunization Practices revised its recommendations for administration of

rubella-containing vaccines to change the recommended interval between receiving MMR vaccine and becoming pregnant from 3 months to 4 weeks ("Revised ACIP Recommendations for Avoiding Pregnancy After Receiving a Rubella-Containing Vaccine" MMWR 50/49, Dec 14, 2001). Interim vaccine information materials reflecting this change were posted on the CDC website on June 13, 2002. Following comments received during the consultation process mandated by the statute, we are proposing slightly different language to further clarify this recommendation through publication of this notice announcing proposed revised MMR vaccine information materials.

We invite written comment on the proposed revisions to the vaccine information materials, entitled "Measles, Mumps & Rubella Vaccines: What You Need to Know." Comments submitted will be considered in finalizing these materials. When the final materials are published in the **Federal Register**, the notice will include an effective date for their use. In the meantime, the interim MMR materials, dated June 13, 2002, which reflect the revised recommendation, can be used in lieu of the 12/16/98 version of the MMR materials.

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Proposed Measles, Mumps & Rubella Vaccine Information Materials

The vaccine information materials, entitled "Measles, Mumps & Rubella Vaccines: What You Need to Know," and dated 12/16/98 and 6/13/02 (interim), are proposed to be revised as follows:

Section 3, "Some people should not get MMR vaccine or should wait." Delete the third bullet and replace it with the following:

"Pregnant women should wait to get MMR vaccine until after they have given birth. Women should avoid getting pregnant for 4 weeks after getting MMR vaccine."

Section 5, "What if there is a moderate or severe reaction?" At the end of the last bullet, add the website address for the Vaccine Adverse Event Reporting System.

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Dated: October 4, 2002.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention.

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